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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NEKTAR THERAPEUTICS,

Plaintiff,

vs.

ELI LILLY & CO.,

Defendant.

CASE NO. 3:23-cv-03943-JD

**PLAINTIFF NEKTAR THERAPEUTICS'
TRIAL BRIEF**

Hon. James Donato

Hearing Date: October 9, 2025

Hearing Time: 1:30 p.m.

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1 Pursuant to the Court’s Standing Order for Civil Trials, Plaintiff Nektar Therapeutics
2 (“Nektar”) submits this Trial Brief “specifying each cause of action and defense remaining to be tried
3 along with a statement of the applicable legal standard.”

4 **I. INTRODUCTION**

5 This case arises from Lilly’s failure to use “Commercially Reasonable Efforts” (“CRE”) to
6 develop and commercialize Rezpeg, Nektar’s promising new drug, and Lilly’s bad faith attempts to
7 delay and thwart Rezpeg’s entry into the market. At trial, Nektar will demonstrate that—far from
8 giving Rezpeg the same “effort, expertise and resources” Lilly used for its other drugs—Lilly instead
9 put Rezpeg on [REDACTED] while advancing its other drugs. Dkt. 228-3, Ex. 16. Even worse, Lilly
10 concealed its bad faith acts by inventing excuses that, as Lilly’s lead scientist secretly admitted to
11 colleagues, did not [REDACTED] *Id.*

12 Contemporaneous evidence will show that Lilly breached its CRE obligation in several ways,
13 including by subjecting Rezpeg to different standards, providing it with less oversight and careful
14 statistical analysis, delaying Rezpeg to favor preferred Lilly drugs, abandoning funded and approved
15 trials, designing trials in abnormal ways that made failure more likely, and failing to advance Rezpeg
16 even after it showed market leading efficacy. Perhaps most tellingly, Lilly’s internal communications
17 include shockingly frank discussion of Lilly’s efforts to delay Rezpeg while keeping Nektar in the
18 dark, which employees celebrated as a way to [REDACTED] *Id.*, Ex. 15.

19 Documents and testimony will further show that Lilly breached its obligation to follow Good
20 Research Practices in developing Rezpeg. Among other things, Lilly failed to perform standard data
21 checks when analyzing data from Rezpeg’s trials and failed to assign qualified personnel to perform
22 such checks, resulting in Lilly publishing inaccurate data dramatically underestimating Rezpeg’s
23 efficacy. Lilly also failed to return critical materials to Nektar after terminating the License
24 Agreement despite promising to do so.

25 Lilly seeks to justify its bad acts by pointing to unsupportable legal defenses and red herring
26 factual issues. Lilly’s legal arguments will fail on summary judgment, and its factual defenses will
27 fail at trial. No court has ever endorsed Lilly’s legal arguments, including the unsupported claim that
28 so-called “judgments” can never violate an efforts clause. In briefing to date, Lilly has been unable to

1 identify any law supporting its claim that Lilly could avoid its CRE obligation by labeling its breaches
 2 “decisions” or “judgments.” Lilly’s damages arguments fare no better. Its argument that Nektar
 3 cannot recover for pre-termination breaches, regardless of Lilly’s conduct or whether Nektar was
 4 harmed, because Lilly terminated the License Agreement before milestone and royalty payments
 5 became due, would create new law transforming a termination clause into a “get out of jail free” card.
 6 Here, again, Lilly cannot identify any law supporting its claim that a party can breach, cause harm,
 7 and avoid liability by remembering to terminate on the right day.

8 Lilly’s fact-based defenses are equally flawed. Lilly argues that Nektar knew of all of Lilly’s
 9 acts (wrong or right) in an effort to share the blame with Nektar, but Lilly’s undisputable own
 10 admissions show that Lilly kept Nektar in the dark by [REDACTED] to ensure Nektar [REDACTED]
 11 [REDACTED] *Id.*, Ex. 18, 25. And while Lilly now points to injection site reactions (“ISR”) from Rezpeg
 12 as justifying its lengthy delays to Rezpeg’s development, that excuse cannot be squared with Lilly’s
 13 continued development of drugs to treat the same disease as Rezpeg that caused much more serious
 14 side effects, including cancer and even death.

15 Nektar looks forward to proving its claims, and the significant harm Lilly caused, at trial.

16 **II. NEKTAR’S CAUSES OF ACTION**

17 Nektar brings claims against Lilly for breach of contract (First Cause of Action) and breach of
 18 the implied covenant of good faith and fair dealing (Second Cause of Action). *See generally* Dkt. 62-
 19 2. On May 22, 2025, Lilly moved for summary judgment, seeking complete dismissal of Nektar’s
 20 claims. Dkt. 210-1. Lilly’s motion for summary judgment is pending and should be denied in full.

21 Lilly previously asserted counterclaims against Nektar for breach of contract and defamation,
 22 Dkt. 54, and vigorously disputed Nektar’s motion for summary judgment on those claims. Dkt. 226.
 23 Nonetheless, on September 19, 2025, Lilly voluntarily moved to dismiss its claims with prejudice.
 24 Dkt. 252. Nektar filed its response on September 23, 2025. Dkt. 254.

25 **A. Breach of Contract**

26 Nektar’s breach of contract claim is based on several of Lilly’s violations of the License
 27 Agreement. *See* Dkt. 62-2, ¶¶ 81-108. These violations include Lilly’s failures to: (1) use CRE to
 28 develop Rezpeg; (2) follow Lilly’s Good Research Practices in developing Rezpeg; and (3) transfer

1 materials to Nektar necessary or useful for Rezpeg's continued development after the License
2 Agreement was terminated.

3 New York law governs the License Agreement, Dkt. 228-2, Ex. 1 § 12.12, and the parties
4 agree that New York law applies. Dkt. 210-1 at 1. A claim for breach of contract requires the
5 existence of a contract, plaintiff's performance, defendant's breach, and resulting damages. *MBIA Ins.*
6 *Corp. v. Patriarch Partners VIII, LLC*, 950 F. Supp. 2d 568, 612 (S.D.N.Y. 2013).

7 For the first two elements, there is no dispute that the parties' License Agreement is a valid
8 contract and that Nektar performed under it. To prove the third element, Nektar will introduce
9 evidence showing Lilly's clear breaches, including evidence that Lilly, among other things:

- 10 • Delayed Rezpeg's development in atopic dermatitis for years despite its
11 clear evidence of efficacy in that indication while advancing worse-
performing drugs;
- 12 • Changed Rezpeg's Phase 2 atopic dermatitis [REDACTED] tion in a way
13 that internal Lilly emails confess did not make [REDACTED] delayed
the trial, and differed from Lilly's treatment of similar drugs;
- 14 • Abandoned a funded and approved trial for Rezpeg, which Lilly did not do
15 for other drugs;
- 16 • Proposed a radical design for Rezpeg's Phase 2 atopic dermatitis trial
designed to enable a [REDACTED] of Rezpeg despite rejecting a similar
17 design for a comparable drug;
- 18 • Failed to supervise its subcontractor and assigned unqualified personnel to
oversee statistical analysis from Rezpeg's trials, leading to miscalculations
19 and publication of inaccurate efficacy data (no such blunder was made for
similar drugs);
- 20 • Decided to terminate Rezpeg's development as a lupus drug despite
21 market-leading efficacy [REDACTED] and
before Lilly had even [REDACTED]
22 and
- 23 • [REDACTED] in favor of advancing other Lilly drugs.

24 The last element, damages, is easily met: Nektar need only show the existence of damages
25 with "reasonable certainty" and provide a "stable foundation for a reasonable estimate" of the amount.
26 *Tractebel Energy Mktg., Inc. v. AEP Power Mktg., Inc.*, 487 F.3d 89, 110 (2d Cir. 2007). This is not a
27 high bar: damages just cannot be "merely speculative, possible, and imaginary." *Id.* Further, "when
28 it is certain that damages have been caused by a breach of contract, and the only uncertainty is as to

1 their amount, there can rarely be good reason for refusing, on account of such uncertainty, any
 2 damages whatever for the breach.” *Id.*; *see also Contemp. Mission, Inc. v. Famous Music Corp.*, 557
 3 F.2d 918, 926 (2d Cir. 1977) (“[U]nder the long-standing New York rule, when the existence of
 4 damage is certain, and the only uncertainty is as to its amount, the plaintiff will not be denied a
 5 recovery of substantial damages [T]he party who has caused the loss may not insist on
 6 theoretical perfection.”).

7 Nektar will surpass this standard. At trial, Nektar will introduce evidence from fact and expert
 8 witnesses establishing how Lilly’s breaches caused harm, including by diminishing Rezpeg’s value
 9 and impairing Nektar’s expectation interest in receiving milestone and royalty payments under the
 10 License Agreement. Nektar will further demonstrate the harm Nektar suffered in the form of
 11 additional clinical trial costs it had to incur because of Lilly’s breaches, as well as damages from
 12 Lilly’s failure to return Rezpeg materials. Notably, Lilly has no expert analysis disputing Nektar’s
 13 damages model; its statistician is unqualified to opine on pharmaceutical development cases, and
 14 instead simply shows the impact of adjustments to Nektar’s model.

15 **B. Breach of the Implied Covenant of Good Faith and Fair Dealing**

16 Nektar’s breach of the implied covenant of good faith and fair dealing claim, *see* Dkt. 62-2, ¶¶
 17 109-117, is also governed by New York law. “In New York, all contracts imply a covenant of good
 18 faith and fair dealing in the course of performance.” *511 W. 232nd Owners Corp. v. Jennifer Realty*
 19 *Co.*, 98 N.Y.2d 144, 153 (2002). Implied covenant claims are properly brought alongside breach of
 20 contract claims when they are brought in the alternative; the implied covenant can be breached by
 21 improper conduct that does not breach an express provision. *See Sorotzkin v. EmblemHealth Inc.*,
 22 2023 WL 7383169, at *2 (2d Cir. Nov. 8, 2023) (“And the only reason the district court provided for
 23 dismissing the implied covenant claim was that it duplicated the express breach claim . . . But if the
 24 allegedly improper conduct did not breach an express contractual provision, that is precisely the
 25 circumstance in which a party may maintain a claim for breach of the implied covenant.”).

26 The implied covenant “is breached when a party acts in a manner that deprives the other party
 27 of the benefits of the contract.” *Frydman v. Endurance Am. Ins. Co.*, 228 N.Y.S.3d 614, 615 (App.
 28 Div. 2025). The elements of this claim are: (1) existence of a contract; (2) that the defendant acted in

1 a manner that deprived the plaintiff of the benefits of the contract; and (3) resulting damages. *See*
 2 N.Y. Civil Pattern Jury Instructions, § 4:1, VII. Z.

3 There is overwhelming evidence that Lilly breached the implied covenant, including
 4 documentary and testimonial evidence that Lilly: (1) delayed Rezpeg’s development and hid timelines
 5 from Nektar; and (2) terminated Rezpeg’s development as a lupus drug without any reasoned analysis.

6 Nektar will also establish how Lilly’s breach has caused damages, including (1) the diminution
 7 in Rezpeg’s value due to Lilly’s breaches; (2) lost milestone and royalty payments; (3) trial costs
 8 Nektar has incurred; and (4) Lilly’s failure to return Rezpeg materials.

9 **III. LILLY’S DEFENSES**

10 **A. Affirmative Defenses**

11 Affirmative defenses are generally subject to the same pleading standard that governs
 12 complaints. *Trans Bay Cable LLC v. M/V Ocean Life*, 2015 WL 7075618, at *4 (N.D. Cal. Nov. 13,
 13 2015) (Donato, J.). Affirmative defenses must be pled with sufficient factual content to provide fair
 14 notice. *Id.*; *Inn S.F. Enter., Inc. v. Ninth Street Lodging, LLC*, 2016 WL 8469189, at *2 (N.D. Cal.
 15 Dec. 19, 2016) (Donato, J.). A “defense that makes mere reference to a legal doctrine, absent some
 16 fact or argument explaining the defense, generally does not provide fair notice.” *Inn S.F. Enter., Inc.*,
 17 2016 WL 8469189, at *2 (cleaned up).

18 In its Answer, Lilly purported to assert two affirmative defenses. On June 20, 2024, the Court
 19 granted Nektar’s motion to strike Lilly’s second affirmative defense, Dkt. 77, leaving only Lilly’s first
 20 affirmative defense at issue.

21 Lilly’s first affirmative defense was “the doctrine of waiver and/or estoppel.” Dkt. 54 at 38.
 22 But beyond reciting this doctrine in a single sentence, Lilly has not provided any information about
 23 what it believes Nektar “waived” or is “estopped” from. This Court has found that a single sentence
 24 like this merely referring to a legal doctrine is insufficient to plead an affirmative defense. *Inn S.F.*
 25 *Enter., Inc.*, 2016 WL 8469189, at *2; *see also Trans Bay Cable LLC*, 2015 WL 7075618, at *4 (N.D.
 26 Cal. Nov. 13, 2015); *Desert Eur. Motorcars, Ltd. v. Desert Eur. Motorcars, Inc.*, 2011 WL 3809933,
 27 at *8 (C.D. Cal. Aug. 25, 2011). For the same reasons, Lilly should not be able to pursue this
 28 affirmative defense at trial.

Moreover, the License Agreement provides that:

The waiver by a Party of a breach or a default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of a Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party. No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving Party.

Dkt. 228-2, Ex. 1 § 12.13. Thus, to the extent the Court finds Lilly has pleaded this defense with requisite specificity (it has not), it presents a simple matter that the Court can dispose of outside the presence of the jury through review of the License Agreement.

B. Other Defenses

In the parties' Joint Pretrial Statement, Lilly raises several legal arguments that it alleges preclude Nektar's claims, as if those arguments were matters for trial. *See* Joint Pretrial Statement (filed contemporaneously herewith) at 4-8. This includes Lilly's arguments that (1) terminating the License Agreement before milestone and royalty payments were due absolves Lilly from paying damages for pre-termination breaches; (2) Nektar's damages are supposedly barred by the License Agreement's liability limitation provision; and (3) "judgments" and "decisions" cannot violate the CRE clause. *Id.* These arguments are for the Court, not the jury, and have no role at trial. *Stoyas v. Toshiba Corp.*, 734 F. Supp. 3d 1000, 1007 (C.D. Cal. 2024) (legal questions are for court, not the jury). Nektar briefly addresses Lilly's legal arguments below, as well as its baseless factual defenses. *See also* Dkt. 228-1 (Nektar Opposition to Lilly Motion for Summary Judgment).

1. The Termination Clause Does Not Prevent Recovery of Milestones and Royalties

Lilly wrongly contends that lost milestone and royalty payments are precluded by its right to terminate the License Agreement. *See* Dkt. 210-1 at 12-13. But as Nektar explained in its opposition, (1) Nektar seeks only payments that would have been "available" absent breaches that took place long before the termination; (2) Lilly's termination right is not a "get out of jail free" card that relieves Lilly from paying damages for pre-termination breaches; and (3) courts applying New York law award damages even where the agreement was terminated. *See* Dkt. 228-1 at 23-25.

1 For example, in *ChemImage Corp. v. Johnson & Johnson*, 2025 WL 1883908, at *1, 5, 24
 2 (S.D.N.Y. July 8, 2025), a case involving an early-stage medical device, the Court found that the
 3 plaintiff had an expectation interest in receiving future milestone and royalty payments through 2039,
 4 even though the agreement at issue had an at-will termination clause and was terminated. Lilly has no
 5 response to *ChemImage* or any of Nektar’s damages cases.

6 **2. Nektar’s Damages Claims Are Not Barred by the Liability Limitation** 7 **Clause**

8 Lilly wrongly argues Nektar’s damages claims amount to a “lost profit analysis” precluded by
 9 a provision of the License Agreement that precludes several types of “special damages, including lost
 10 profits.” *See* Dkt. 210-1 at 13-14. But as Nektar explained in its opposition, that argument depends
 11 on at least three unsupported and incorrect assumptions: (1) diminution in value is the same as “lost
 12 profits” (it is not); (2) the liability provision in the License Agreement precludes recovery of general
 13 damages (it does not); and (3) the provision’s exception for “damages arising out of the gross
 14 negligence or willful misconduct of the liable party” does not apply (it does). *See* Dkt. 228-1 at 19-23.

15 Indeed, multiple courts applying New York law have directly rejected the argument Lilly
 16 raises. *See, e.g., ChemImage*, 2025 WL 1883908, at *21 (S.D.N.Y. July 8, 2025) (rejecting argument
 17 that damages based on diminution in value of an early-stage medical device, including expectation
 18 interest in future earnout and royalty payments, was barred by a consequential damages waiver); *N.*
 19 *Am. Photon Infotech Ltd. v. ZoomInfo LLC*, 2021 WL 4482208, at *7 (S.D.N.Y. Sept. 30, 2021)
 20 (concluding damages for diminution in value of an asset “is not the same of lost profits” and rejecting
 21 argument that diminution in value damages were barred by consequential damages waiver).

22 Further, even if Nektar’s diminution in value damages claim were somehow “lost profits” (it is
 23 not), the License Agreement’s liability limitation provision does not apply where Lilly acted with
 24 gross negligence or willful misconduct. Dkt. 228-2 § 10.6. At trial, Nektar will present significant
 25 evidence showing Lilly’s actions constituted gross negligence or willful misconduct. Dkt. 228-1 at 4-
 26 13.

3. Lilly's Judgments and Decisions Can Violate the Commercially Reasonable Efforts Clause

Lilly incorrectly contends that Nektar's breach of contract claim is barred because the "commercially reasonable efforts" clause speaks to "efforts," and not decision-making and "judgments." Dkt. 210-1 at 2-3, 6, 15. But as Nektar explained in its opposition, Nektar's claims are tied to more than just "decisions." *See* Dkt. 228-1 at 13-17. The License Agreement's plain text also forecloses Lilly's argument, including because Lilly was obligated to develop and commercialize Rezpeg in light of "the factors normally considered by [Lilly] in making product portfolio decisions." Dkt. 228-2 at 3-4. Further, several courts have squarely rejected Lilly's argument and ruled that a party's decisions violated a "commercially reasonable efforts" clause. *See* Dkt. 228-1 at 13-17. Indeed, Lilly's principal authority, *InspiRx, Inc. v. Lupin Atlantis Holdings SA*, 554 F. Supp. 3d 542 (S.D.N.Y. 2021) (*see* Dkt. 210-1 at 15), undermines its position because the court there took as its task to "examine whether [defendant's] decision[s] . . . were commercially reasonable." *Id.* at 555.

4. Nektar Did Not Approve of Lilly's Breaches

At trial, Lilly will attempt to establish that Nektar knew and approved of Lilly's actions it now alleges breached the License Agreement. For example, Lilly claims that Nektar "agreed to" the criteria that Lilly used to terminate Rezpeg's development as a lupus treatment. *See* Joint Pretrial Statement at 6-7. But Nektar will establish that Lilly did not even follow the supposed criteria Lilly points to. Rather, Nektar will show that Rezpeg met a "high critical success factor" that Lilly set in its Phase 2 lupus trial but was terminated anyway. Lilly cannot identify another lupus drug it has terminated after [REDACTED] in a trial, because there is none. Nektar will further show that Rezpeg had the potential for market leading efficacy as a lupus treatment and could dramatically benefit lupus patients (who have no effective treatment options)—facts Lilly would have known had Lilly properly analyzed the data from Rezpeg's Phase 2 lupus trial.

5. Lilly's Injection Site Reaction Defense Will Fail

Lilly will further argue that intentionally delaying Rezpeg and treating Rezpeg differently from its other drugs was justified because Rezpeg administration led to non-medically serious, transient ISRs—generally redness at the injection site—in some clinical trial patients. Joint Pretrial Statement

1 at 6 (claiming patients “don’t want” treatments that cause ISRs because competitor treatments do not
2 cause them). Lilly’s argument will fail at trial. Nektar will establish that prescribing decisions are
3 based on factors beyond whether a drug causes an ISR (including efficacy and whether the drug
4 causes other, more serious side effects), and that Lilly’s own expert consultants told Lilly ISRs would
5 not prevent Rezpeg’s widespread adoption. Further, Lilly’s fixation on ISRs as a basis to delay and
6 terminate Rezpeg’s development cannot be reconciled with its continued development of less
7 efficacious comparator drugs with worse side effects, like conjunctivitis and cancer.

8
9 DATED: September 25, 2025

Respectfully submitted,

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ATTESTATION PURSUANT TO CIVIL L.R. 5-1(I)(3)

I, John (“Mickey”) McCauley, am the ECF user whose user ID and password are being used to file this document. I hereby attest that concurrence in the filing of this document has been obtained from each of the other signatories.

By /s/ John McCauley
John McCauley